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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,463	10/01/2003	Myriam Kauffmann	231179US26	5489

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EXAMINER	
APANIUS, MICHAEL	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/674,463	KAUFFMANN ET AL.	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *4,5,18,20-33,38 and 43-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-17,19,34-37 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/1/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10012003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1 (claims 1-19 and 21-45) and Species 1 (figures 1-6) in the reply filed on 23 March 2006 is acknowledged.

2. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim.

3. Claims 4, 5, 18, 21-33, 38 and 43-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant submitted that claims 1-19 and 21-43 are readable on Species 1. However, the Examiner submits that only claims 1-3, 6-17, 19, 34-37 and 39-42 are readable on Species 1. Claims 4, 21 and 38 recite that the reagent is inside the volume of the tube/container. However, Species 1 is directed to a tube/container having an analyte-taking liquid within the tube/container and the reagent being provided on a plurality of strips (see figures 1-6 and paragraphs 43-57). Claims 5 and 22-33 depend from claims 4 and 21, respectively, and therefore also do not read on Species 1. Note that the species directed to figure 7 includes a tube/container filled with a reagent (paragraphs 58 and 59). Claims 18 and 43 recite at least one packaging bag and a string of bags, respectively. Species 1 shows packaging comprising a box. Therefore, claims 18 and 43 do not read on Species 1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10, 36, 37 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 10 contains the trademark/trade name NYLON. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a material and, accordingly, the identification/description is indefinite.

7. At claim 36, "said solution" lacks proper antecedent basis in the claims.

8. At claim 40, line 2, "said second position" lacks proper antecedent basis in the claims. Furthermore, it appears that the second end would have a second position, not the first open end as stated in the claim.

9. At claim 41, line 1, "said container" lacks proper antecedent basis in the claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 6-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsao (US 5,702,035). Tsao discloses an analyte-taking device comprising: a tube (61) provided at one end with an analyte-taking element (62); a plug (66) inside the tube; and at least one liquid (64) contained in an inside space of the tube separated from the analyte-taking element at least by the plug, the plug being arranged, in use, to be expelled together with the liquid towards the analyte-taking element, wherein the liquid is an analyte-taking liquid for facilitating a taking of at least one analyte by the analyte-taking element. In regards to claims 2 and 3, the liquid is an alcohol (column 4, line 6). In regards to claims 6-8, the analyte-taking element is a porous, fibrous, cotton bud (column 3, lines 34-38). In regards to claims 9, 10 and 15, the plug is a liquid silicone comprising silicone dioxide (column 4, lines 1-3). In regards to claim 11, the tube has a break-off portion (63) which can be broken (column 2, lines 25-27). In regards to claim 12, the device is deemed to have a retaining element which retains the break-off portion as shown in figure 1.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 16, 17, 19, 34-37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsao (US 5,702,035) in view of Caillouette (US 6,402,705). Tsao discloses the limitations of the above claims as stated above and that the device is suitable for many applications (column 4, lines 12-13). However, Tsao does not expressly disclose a plurality of analyte-taking devices combined with a reagent and packaging. Caillouette teaches the use of a plurality analyte-taking devices (14) with a plurality of reagent strips (54 in figure 4) which produce an observable reaction and a box (25) comprising a compartment for the purpose of analyzing an analyte for diagnostic purposes (column 4, lines 45-48) and to provide verification of test results (column 4, lines 56-60). It would have been obvious to one having ordinary skill in the art at the time of invention to have packaged swabs of Tsao with reagent strips as taught by Caillouette in order to analyze an analyte for diagnostic purposes and further allowing for verification by providing multiple testing in one package.

14. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsao (US 5,702,035) in view of Tobin et al. (US 3,792,699). Tsao does not expressly disclose the volume of the liquid. Tobin teaches that for a swab, a volume of

liquid between 0.5-1mL is a preferable because it is just sufficient to moisten the swab tip (column 3, lines 21-25). It would have been obvious to one having ordinary skill in the art at the time of invention to have used a between 0.5-1mL of liquid as taught by Tobin in the device of Tsao in order to provide just enough liquid to sufficiently moisten the swab tip.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,707,450 discloses a specimen collection and test unit. US 5,364,792 discloses a test swab with test reagents. US 5,869,003 discloses a self contained diagnostic test unit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA

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